VAMHCS RESEARCH SERVICE HOT TOPIC

Vol. 7 No. 1
January 15, 2013

2012 Research Year in Review: Reminders for Research Compliance in 2013

In 2012, a number of fundamental changes occurred in the processes for submitting and conducting VA research projects. The changes were communicated to the research community through "Research Service Hot Topics" and "Lunch & Learn" sessions.

The R&D Service frequently finds problems with investigators' implementation of the changes or with knowledge of the changes. The purpose of this Research Service Hot Topic is to remind the human research community of the changes. By doing so, we hope to assist you in maintaining compliance with VA research processes.

All the Hot Topics and Bulletins referenced below can be found in the archive on the Research Service website and are also linked in the items below.

The following topics are covered in this Hot Topic:

- Collaborative Studies Program [Vol.6 No.1]
- New VAMHCS Research informed Consent Template [Bulletin 16, 11/5/12]
- Annual updates of exempt studies and other research activities. [Vol.6 No.2]
- Closing VA research studies [Vol.6 No.4]
- Allowable signatures [Vol.6 No.3]
- Take care in completing VA HIPPAA Authorizations
- Contact information for principal investigator on VA HIPPAA Authorization
- Accounting of disclosures [Vol.6 No.6]
- Requirement to report serious adverse events (SAEs) [Vol.6 No.5]

- Collaborative Studies Program [Vol.6 No.1].
  - Please see the archived Hot Topic for details.
  - **The main goal of these requirements** is for research projects to clearly define what is done at or through the VA and what is done at or through our affiliated university. By defining studies in this way, it is expected that
    - ownership of data and sharing agreements will be more clearly established,
    - liability & compensation for participant injury will depend on the location/practitioner in which the injury occurs,
    - research informed consent forms and HIPAA authorizations will be more informative to participants.
  - If you are an investigator with a dual appointment and you are conducting or plan to conduct research involving VA resources, you may have a "VA-UM Collaborative Study" and are therefore directly affected by these new requirements.
  - The R&D Committee will not approve any new VA protocol that has not satisfactorily addressed the "collaborative studies" issue.
  - Because of the transition to the new VA ICF (see below), collaborative studies issues may now need to be addressed at the time of continuing review as well.

- Contact the Research Service for assistance or a 'pre-review' of your protocol by the "collaborative studies working group'.

- New VAMHCS Research informed Consent Template [Bulletin 16, 11/5/12]. This template **changes the content** of the VA Informed Consent Form including some required statements for the VA and some prompts for additional information when applicable, especially with regard to "collaborative" protocols.
  - Please see the archived bulletin for details.
  - This template can be differentiated from the prior template by the presence of the following version date in the lower right corner of the footer: "VAMHCS template v. 103012".
  - This new template is now required for **all new studies**, **all continuing reviews**, and **all modifications to informed consent forms**.
  - **This template is not simply a copy-paste of the content used in the UM version**. Be very careful to look through the prompts and comments in the template and answer them as applicable for the VA portions of your studies.
  - Carefully consider the implications brought on by the 'collaborative studies' program (see above): you may have to significantly change some sections of your current ICF! You may even have to modify some sections in CICERO!
  - The "University Statement" and contact information for the HARPO has changed with this version of the ICF, so do not simply paste in from your past versions. Do not forget the statement prior to the University statement in which it is explained to the participant that the UM is the VAMHCS' designated IRB. And take note that the contact for the Research Service at the end of the ICF is the HARPO (with change in room number), not the RCO.

- Annual updates of exempt studies and other research activities. [Vol.6 No.2].
  - Even IRB-exempt studies and 'not human research' studies need to be sent to VAMHCS R&D Committee (RDC) for annual review.

- Closing VA research studies [Vol.6 No.4].
  - Remember to close your study at the VAMHCS R&D Committee and in CPRS as well as at the IRB.
  - Close or modify the study at RDC as soon as you have closed the IRB component of the study.
  - It is possible for a VA study to close its human component at the IRB but its animal or laboratory components may remain open at the VA.
  - See Hot Topic Vol.6 No.4 for details.

- HIPAA
  - Allowable signatures [Vol.6 No.3].
    - Protocols that enroll decisionally impaired subjects may need two different individuals as signatories for the research Informed Consent and the HIPAA Authorization. VA rules for Legally Authorized Representative (LAR) to sign informed consent ARE DIFFERENT FROM the VA rules for a Personal Representative who is allowed to sign HIPAA authorizations for decisionally impaired participants.
    - If you believe your study could involve participation of decisionally impaired individuals *and,* if use or disclosure of PHI is required for your project, *and* if you will not be able to guarantee that you will always have a DPA or legal guardian who is

the LAR, then you should request a waiver or alteration of HIPAA authorization from the IRB for your study.
    - See Hot Topic Vol.6 No.3 for details.
- Take care in completing VA HIPPAA Authorizations.
    - There has been a new template since August 2011. Be sure that you use the template with "Version: 08.11.2011" in the footer.
    - Be aware that the template offers choices & suggestions in how you might complete the various sections. You must decide on which items apply to your study and delete the others. You might also need to add items if applicable to your study.
    - For example, for studies completely conducted at the VAMHCS, it is unlikely that entities at the University will use, obtain, disclose, or store PHI.
    - If the University is the "local coordinating center" for the study, then the HIPAA authorization must make it clear to the participant that the data will be disclosed to the UM (Coordinating Center) where the data will be combined and analyzed for the "collaborative" study.
- Contact information for principal investigator on VA HIPPAA Authorization.
    - PI's contact information must state his/her **VA** association (not solely your UM association).
    - Even if your office address & phone number is at the University, you must state your association with the VA. For example: 'VAMHCS Medical Service', 'VAMHCS Oncology Service' + VA address of the clinic, etc.
- Accounting of disclosures [Vol.6 No.6].
    - Investigators are required to track disclosures of any individually identifiable information whenever they release information to their research participants or to third parties (personal physicians, etc.
    - The details on how investigators must comply with this requirement are specified in Hot Topic Vol.6 No.6.
    - **This requirement has been in effect since November 2012**. The Privacy Office performs quarterly audits on this requirement.

- Requirement to report serious adverse events (SAEs) [Vol.6 No.5].
    - For your VA research projects, report all local or internal unanticipated serious adverse events to the IRB within 5 business days of becoming aware of the event, even if you believe that the event is unrelated to the study.
    - Submit the information to the IRB through the RNI pathway in CICERO, Item 13.

The attachments to this Hot Topic will be posted on the Forms page of the Research Service website:
http://www.maryland.research.va.gov/research/human/human_subject_forms.asp

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:

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Can’t put your finger on a past Hot Topic you know would solve your problem? No problem. Check the Hot Topics archive on the Research Service website:
http://www.maryland.research.va.gov/hot_topics.asp

For comments, complaints or suggestions regarding the Research Service, contact:

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